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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,346	10/21/2003	Josephus Christianus Maria Smeekens	ARNO121867	6649

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EXAMINER

PAGE, BRENT T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,346	Applicant(s) SMEEKENS ET AL.	
	Examiner Brent Page	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-34 is/are pending in the application.
- 4a) Of the above claim(s) 25-30 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/019,385.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/21/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group II in the reply filed on 07/12/2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-24 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method for producing oligosaccharides having low degree of polymerization and a method for producing food products comprising selecting any gene coding for any fructosyltransferase enzyme, linking the gene to suitable transcription-initiation and termination signals to provide an expression construct, and transforming any mutant of any species of plant cell with said expression construct.

In contrast the specification only provides guidance for transforming *Nicotiana plumbaginifolia* with the full length 6-SFT gene from Barley. The specification does not provide guidance for any mutant forms of *Nicotiana plumbaginifolia*, or any other species or any other mutant species transformed

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with any other fructosyltransferase genes resulting in oligosaccharides with a low degree of polymerization.

The function of different 1-FFT genes is unpredictable. Vergauwen et al (Plant Physiology 2003, 133:391-401) in a review of the role of 1-FFT in Inulin production of different species found that very different degrees of polymerization were found among different species of plants, in particular chicory and globe thistle (see page 391 second full paragraph, and page 399, second and third full paragraphs). In addition not all 1-FFT genes have been characterized in all plant species, or for that matter in other species as broadly claimed and therefore undue experimentation would be required to isolate, sequence, and characterize the enzymatic function of all 1-FFT genes of all species.

The specification also does not provide any guidance for functional domains of either 1-FFT genes or SST genes, or the amount of conservation in DNA sequence required for activity of the enzymes encoded by the DNA sequences. Without this guidance, undue experimentation would be required to determine all the embodiments of all 1-FFT and SST genes that are sufficient to express a protein capable of producing oligosaccharides having a low degree of polymerization. In a study of the functional domains for fructosyl transferases, Ritsema et al (2004 Plant Molecular Biology 54:853-863) discovered that switching the sucrose binding boxes of FFT, SST, and invertase, along with site directed mutagenesis resulted in different fructosyl transferase activity and function (see page 857 last full paragraph, page 859 last two full paragraphs, for example). Caimi et al (WO 95/13389) disclose that point mutations in the

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bacterial fructosyltransferase gene, FTF, transformed into tomato plants resulted in viable, apparent full length RNA transcripts, but are not translated into functional FTF proteins (see page 43, line 8 through page 44 line 8 for example). Furthermore, undue experimentation would be required of one of skill in the art to evaluate all such genes as described above for their affect in all plant species, including all mutant phenotypes with altered starch or sucrose metabolism, given that such an evaluation would also require evaluation of all fructosyltransferase genes and all starch biosynthesis genes of all plant species.

The viability of transgenic plants that accumulate oligosaccharides is unpredictable. Turk et al (1997 New Phytology 136:29-38) disclose transgenic tobacco plants transformed with the E. coli levansucrase gene may have deleterious defects in the form of bleached leaves, stunted growth and reduced root growth (see page 36 last paragraph, for example). Caimi et al (WO 95/13389) disclose the lack of viability in shoots of transgenic tobacco plants that were transformed with the bacterial fructosyltransferase gene SacB (see page 68 lines 18-33, for example).

Given the state of the art, and the lack of guidance as discussed above, undue experimentation would be required to evaluate all fructosyltransferase coding sequences for their effect on oligosaccharide production and plant viability of all plant species and all naturally occurring and molecularly modified mutant plant species as broadly claimed.

Claims 22-24 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain

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subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method for producing oligosaccharides having low degree of polymerization and a method for producing food products comprising selecting any gene coding for any fructosyltransferase enzyme, linking the gene to suitable transcription-initiation and termination signals to provide an expression construct, and transforming any mutant of any species of plant cell with said expression construct.

In contrast the specification only provides guidance for transforming *Nicotiana plumbaginifolia* with the full length 6-SFT gene from Barley. The specification does not provide guidance for any mutant forms of *Nicotiana plumbaginifolia*, or any other species or any other mutant species transformed with any other fructosyltransferase genes resulting in oligosaccharides with a low degree of polymerization.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

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Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming

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plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The claims are free of the prior art given the failure of the prior art to teach or reasonably suggest a method for producing oligosaccharides having a low degree of polymerization or a method of for producing food products comprising said oligosaccharides as a sugar substitute, comprising transforming a plant cell from a mutant plant having an altered starch or sucrose metabolism with an expression vector comprising a gene encoding a fructosyltransferase gene, regenerating a transgenic plant from the plant cell, culturing the transgenic plant and isolating oligosaccharides from the plant.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

